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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/528,742	03/20/2000	Paul Roben	11390-002001	5781

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EXAMINER

WOITACH, JOSEPH T

ART UNIT	PAPER NUMBER
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1632

DATE MAILED: 06/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/528,742

Applicant(s)

ROBEN ET AL.

Examiner

Joseph T. Weitach

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 April 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10, 13, 16, 19-32, 36, 39-46, 49, 51 and 56-63 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10, 13, 16, 19-32, 36, 39-46, 49, 51, 56-63 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

This application filed March 20, 2000, claims benefit to provisional application 60/139,579, filed June 17, 1999.

Applicants' amendment, filed April 1, 2004, has been received and entered. The specification has been amended. Claims 11, 12, 14, 15, 17, 18, 33-35, 37, 38, 47, 48, 50, 52-54 have been canceled. Claims 1, 2, 19, 20, 21, 27, 30, 40, 43-46, 49, 51, 56 and 57 have been amended. Claims 62 and 63 have been added. Claims 1-10, 13, 16, 19-30, 32, 36, 39-46, 49, 51 and 56-63 are pending.

Election/Restriction

As indicated in the previous office action, the election of species of a specific (a) labeling domain and (b) specific binding domain is withdrawn. Newly added claims 62 and 63 are drawn to the elected invention. Claims 1-10, 13, 16, 19-30, 32, 36, 39-46, 49, 51 and 56-63 are currently under examination.

It is noted that claims 1 and 19 have been amended to recite several specific types of bonds instead of a bond set forth by functional limitations. Since there are only five different types of bonds now recited and encompassed by the claims it would not constitute an undue burden to examine each of these in the instant action. The elected species of the cleavable moiety dithiopropionate has now been rejoined and extended to each of the types of bonds recited in the claims.

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Claim Objections

Claim 57 objected to because it is dependent on canceled claim 11 is withdrawn.

Amendment to the claim to be dependent on claim 10 a pending claim has obviated the basis of the objection.

Claims 1, 19, 30, 51 objected to because the claims recite and encompass species which were not specifically elected is withdrawn.

Specification

The objection to the amendment filed September 10, 2002, paper number 16, is withdrawn.

The amendment to the specification to remove the recitation of "the disclosure of which is incorporated herein by reference in its entirety" has obviated the basis of the objection.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-10, 13, 14, 16-34, 36-46, 49, 51 and 56-61 rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention is withdrawn.

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The amendment to the independent claims to recite specific species of types of bonds has addressed the basis of the rejection.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-10, 13, 16, 19-30, 32, 36, 39-46, 49, 51 and 56-63 are rejected under 35 U.S.C.

112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. Specifically, claims 1, 19 and 51 are vague and incomplete because while the preamble of the claim sets forth a method of labeling a protein, step c) only sets forth cleaving conditions, and it is unclear how this step labels the protein. More specifically, because the binding domain and the labeling domain of the molecule used in the methods are separated at the final step it is unclear how and/or what is being labeled. The types of specific labels set forth in dependent claims and the specification do not appear to covalently or non-covalently associate with a protein to which the original impermeable reagent binds. In particular, the first domain is the only domain that is capable of covalently and nonspecifically binding to the protein of interest, so it is unclear how the protein is labeled and how the label is used to isolate the protein when the binding domain and labeling domain are cleaved from one another in step c). As indicated above, none of the specific labeling molecules lead to how the labeling is accomplished and it is unclear if additional steps are required to label the protein before/after the cleaving the impermeable reagent, or alternatively if the label referred to in the preamble is actually the binding domain. More clearly setting forth how the protein is specifically labeled would address the basis of the rejection.

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Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 19-34, 36-45, 49, 51, 57, 58, 60 and 61 rejected under 35 U.S.C. 103(a) as being unpatentable over De La Fuente *et al.* (IDS reference), Hastie *et al.* (IDS ref)., and Rothschild *et al.* (US Patent 5,948,624) and the Pierce Catalog & Handbook, 1994-95 is withdrawn.

As noted by Applicants', the amendment to the claims to encompass cleaving conditions that are non-denaturing differentiates the claimed method from that disclosed or made obvious by the combination of De La Fuente *et al.* Hastie *et al.*, and Rothschild *et al.* and the Pierce Catalog.

Conclusion

No claim is allowed. The claims are free of the art of record, however they are subject to other rejections.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Woitach whose telephone number is (571) 272-0739.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached at (571)272-0734.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group analyst Dianiece Jacobs whose telephone number is (571)272-0532.

Joseph T. Woitach

Joe Woitach
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